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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 11/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/404,010

Applicant(s)

LUO ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 16.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 17 August 2001 and declaration under 37 C.F.R. 1.132, filed 23 October 2001, are acknowledged. Claims 24-33 are pending in this application.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

#### ***Claim Rejections/Objections Withdrawn***

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 1, 2, and 6-10 under 35 U.S.C. 102 is withdrawn in response to Applicant's amendment.
4. The rejection of claims 1, 4, and 6-10 under 35 U.S.C. 112, first paragraph, as lacking written description is withdrawn in response to Applicant's amendment.
5. The rejection of claims 1, 2, and 6-10 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

#### ***Claim Rejections Maintained/New Grounds of Rejection***

6. New claims 24-33 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for reasons of record in paper no. 13, pages 3-5 for claims 1-10.

Applicant argues that Traf4 is amplified in human primary breast cancer and is required for normal cell proliferation. Applicant argues that due to the role of homologous kinases in cell division and the binding of Mkinase to Traf4, one of skill would know how to use the claimed compositions to test for modulators of cell division. Applicant further argues that the claimed compositions have specific, real world, credible utility. Applicant has submitted a declaration pursuant to 37 C.F.R. 1.132. This declaration states that a number of characteristics and

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functions for Mkinase are set forth on pages 4, 5, and 31 of the specification, and that the claimed compositions could be used to identify agents capable of modulating Mkinase activity. Applicant further provides teachings that Mkinase phosphorylates the MAP kinase substrate myelin basic protein.

Applicant's arguments and declaration have been fully considered but have not been found to be persuasive. While, based on Applicant's teachings, one of skill in the art might know how to use Traf4, these teachings do not provide sufficient guidance for the artisan to use Mkinase. One of skill in the art could not extrapolate from the role of Traf4 to that of Mkinase. There are no teachings as to what effect Mkinase itself has on the cell cycle, or as the effects of its interaction with Traf4. There is no indication, for example, as to what physiological substrates Mkinase phosphorylates and what effect this phosphorylation has on the cell cycle. There is no indication as to what effect Traf4 has on the activity of Mkinase. One of skill in the art might conclude that Mkinase is somehow involved in the cell cycle, but would not know how it is involved, and thus would not be able to use the kinase without first experimenting to determine what its role is. Thus one of skill would not be able to use the compositions to screen for modulators without further experimentation, since one of skill would not know what activity would be expected to be modulated. Since the goal is unknown and thus the outcome is unpredictable, such experimentation is undue. That Mkinase is homologous to MAP kinases is not sufficient guidance as to its role; MAP kinases are involved in signalling by most cell-surface receptors and one of skill in the art would not, based only on homology, know how to use this particular kinase.

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Applicant's declaration points to pages 4, 5, and 31 of the specification as asserting a number of characteristics and functions. However, all that is indicated on p. 4-5 with respect to Mkinase is that it has homology to MAP kinases and interacts with Traf4. On p. 31, what is set forth is again the binding to Traf4, as well as general characteristics of cell modulators. There are no teachings as to the particular role of Mkinase, such as whether it arrests or stimulates cell division, or what other effects it has. Applicant indicates that Applicant would expect to use Mkinase compositions for a substantial, credible, real-world utility, such as screening for agents capable of modulating Mkinase activity. However, such a use is not a substantial utility: a substantial utility must be "real-world" and reasonably confirmed. There is no "real world" use associated with the study of modulators of a protein whose significance itself is unknown. This is a research use with the intended goal of discovering how the protein might be used or what use might be associated with the ability to affect it, not a use for the protein itself. Thus, since this is not a substantial utility, its disclosure is not sufficient to teach one of skill how to use the protein. Applicant further states that Mkinase phosphorylates myelin basic protein. Absent evidence that it phosphorylates the same site as MAP kinases, this teaching is not sufficient to identify the protein as a MAP kinase. Further, as stated above, such identification would not provide sufficient guidance for one of skill in the art to use the protein; MAP kinases have different functions.

Thus, since MAP kinases have different functions, since there is no teaching as to how the claimed compositions might affect the cell cycle, and since there is no particular use indicated by the binding of Traf4 to Mkinase, one of skill in the art would not know how to use the claimed invention.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

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All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
November 7, 2001

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